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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,112	05/06/2004	Jaime Simon	61350C	8566

109 7590 11/13/2006

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION,
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/840,112

Applicant(s)

SIMON ET AL.

Examiner

Jagadishwar R. Samala

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10-25-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action was acknowledged May 06, 2004

Claim Disposition

2. Claims 1-23 are pending and are under examination.

Information Disclosure Statement

3. The Information Disclosure Statement filed on October 25, 2004 has been received and entered the references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office Action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Motoki Yonekawa et.al (JP H10-130154 here after '154) or Samejima et al (EP 0,077,956 here after '956) or Berger, deceased et al., (US 4,470,975 here after '975).
6. Claims are directed to a method for treating or removing fluid from the intestinal tract of a host comprising enteric-coated, non-toxic, water-absorbing polymer as active ingredient, wherein the water-absorbing polymer is capable of absorbing at least 10-40 times its weight in physiological saline and wherein is formed by polymerization of

Art Unit: 1618

monomers of acrylates or the polymer is made up of polymerized acrylic acid monomers or salts thereof or the polymer is a polysaccharide.

The patent '154 discloses a method of administering a drug that can improve the life extending ratio of kidney patients and is characterized by including an acrylic type water absorbent monomer as an active component wherein the cross-linked material of the polymer is formed by polymerization or by suspension-dispersing a high concentration aqueous solution of the acrylic acid alkali metal salt or the polymer is a polysaccharide (see page 4, 0007, page 7, 0021 and page 8, 0023). The patent '154 also discloses that acrylic water absorbent resins, said polymer is capable of absorbing ability (volume (mL) of a physiological saline solution absorbed per 1g) is 5 to 100 times (see page, 0026). The patent '154 also discloses a method of administering the drug orally to the patient to absorb-remove the uric acid, water and potassium ions, in an ordinary form that can be obtained, for e.g. the powder form, a bead-like form, a flake-like form, gel-form, tablets, granules, capsules (see page 9, 0027). The patent'154 also discloses the pharmacological studies of the drug for improving the life-extending rate of kidney patients (see pages 15-18).

As to claims 2 or 13, although limitations (i.e., nocturia, fluid-responsive hypertension) require to instant claims are not specifically disclosed through the cited reference, teaching of the patent possesses all the steps required as recited in claims 2 and 13.

The patent '956 discloses an enteric-coated microcapsules comprising water-swallowable polymer material in the core, said polymer is capable of absorbing water (1.2-1.5 times its weight, see page 5, lines 10-22, page 6, line 9 and page 27 lines 1-5). Patent '956 also discloses that the composition in the form of enteric microcapsule is capable of releasing easily the active component in intestinal tract and maintain the active component (core material) effectively in the stomach (see page 2, lines 16-20). The patent '956 also discloses that the composition is in granule formulation (see page 22, line 1-10).

The patent '975 discloses a composition and method of removing fluid or edema by diverting water elimination from the renal route to the gastrointestinal route, and removing excess water from the body by the gastrointestinal tract of an animal by administering to said animal dextrans: a polysaccharide that is a polymer made of monomers of carbohydrate moieties in form of gel grains (see abstract, column 1, line 54-56 and column 10, lines 5-30). Patent '975 also discloses a composition and method for treating abnormal excess accumulation of fluid within the body, such as congestive heart failure, cirrhosis of the liver, nephrosis and other renal diseases associated with fluid retention in said animal (see column 1, lines 63+). The patent '975 also discloses the insoluble hydrophilic, cross-linked polysaccharide polymer may be ingested by the patient and during passage of these substances through the digestive system, water is absorbed or bound tremendously and finally along with bound water, urea in the lumen of the gastrointestinal system is then eliminated by passage from the alimentary canal in

Art Unit: 1618

the normal manner (see column 3, lines 10-27+). Patients with renal failure cannot excrete all of the fluid and electrolytes needing excretion, total body levels of sodium, potassium, calcium, phosphate, chloride, water and various traces minerals ingested in their diet are usually higher than normal. Exclusive fluid retention and abnormal hormonal production causes hypertension. The conventional treatment for diseases of this nature is periodic hemodialysis. Consequently, patients on renal dialysis usually are receiving numerous medications to control their blood pressure, hormonal status, fat levels, and serum chemistries. Thus it has been found that certain insoluble hydrophilic, cross-linked polysaccharides are useful pharmaceutical agents for the treatment of abnormal excess accumulation of fluid within the body, such as, congestive heart failure, cirrhosis of the liver, nephrosis, and other renal diseases associated with fluid retention (see column 1 and 2). Thus teaching of the patents ('154, '956, and '975) possesses all the steps required as recited in claims 2, and 13. Thus all the claims are anticipated.

Conclusion


1. No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



VICKIE KIM
PRIMARY EXAMINER

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr